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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/961,414	09/25/2001	Fumiyasu Hirai	12218/1	6930

7590 03/08/2002  
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EXAMINER

FORD, VANESSA L

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 03/08/2002

Please find below and/or attached an Office communication concerning this application or proceeding.



## Office Action Summary

Application No.

09/961,414

Applicant(s)

HIRAI ET AL.

Examiner

Vanessa L. Ford

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) 1-3 and 5 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 4, 6 and 7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5. 6) ☐ Other: \_\_\_\_\_



### **DETAILED ACTION**

1. Applicant's election of Group II, claim 4 in Paper No. 7, filed on January 16, 2002 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 1-3 and 5 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected invention. Election was made **without** traverse. Claim 4 has been amended. Claims 6 and 7 have been added.

#### ***Specification Objections***

2. The specification is objected to because of the following informalities: The specifications contains brackets (i.e. [ ] ) throughout. The Applicant is asked to submit a substitute specification with the brackets removed.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 4,6 and 7 are indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 4,6 and 7 recite a method for removing enterotoxin from a body fluid. There is no step in the claims which states that the enterotoxin is actually removed.



***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 4 and 6-7 are rejected under 35 U.S.C. 102(a) as anticipated by Hirai et al (*EP 0993 834 A1, published April 19, 2000*)

Claims 4 and 6-7 are drawn to a method for adsorptive removal of an enterotoxin in a body fluid which comprises contacting an enterotoxin-containing body fluid with an enterotoxin adsorbent, said adsorbent comprising a compound with a log P, in which P represents a partition coefficient in an octanol-water system, value of not less than 2.50 as immobilized on a water-insoluble carrier.

Hirai et al teach a method for removing enterotoxin which comprises bringing a body fluid containing an enterotoxin into contact with the adsorbent. Hirai et al teach that the adsorbent comprises a compound which has a log P value of at least 2.50 wherein P is a partition coefficient in an octanol-water system and which is immobilized on a water-insoluble carrier (see the Abstract). Hirai et al teach that the water-insoluble carrier is a water-insoluble porous carrier which has an exclusion limit for globular protein of from  $1 \times 10^4$  to  $60 \times 10^4$  (see page 2). The method of Hirai, et al appears to be the same as the claimed invention.



Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i.e., that the method of the prior art does not possess the same material method steps and parameters of the claimed method). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

5. Claims 4 and 6-7 are rejected under 35 U.S.C. 102(b) as anticipated by Nagaki et al (*Journal of Medical Microbiology*, May 1993, 38(5):354-359).

Claims 4 and 6-7 are drawn to a method for adsorptive removal of an enterotoxin in a body fluid which comprises contacting an enterotoxin-containing body fluid with an enterotoxin adsorbent, said adsorbent comprising a compound with a log P, in which P represents a partition coefficient in an octanol-water system, value of not less than 2.50 as immobilized on a water-insoluble carrier.

Nagaski et al teach a method for adsorptive removal of an enterotoxin in a body fluid which comprises contacting an enterotoxin-containing body fluid with an enterotoxin adsorbent (see the Abstract). Characteristics such as partition coefficient in an octanol water system and a value of not less than 2.50 when immobilized, would be inherent in the material of the prior art. It would be inherent that the adsorbent of the prior art would comprise a compound with a <sup>P</sup> log, in which P represents a partition coefficient in an octanol-water system, value of not less than 2.50 as immobilized on a water-insoluble carrier that has a molecular weight of exclusion limit of 5000 to 600000



for globular protein. The method of Nagaski, et al appears to be the same as the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's method with the method of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed method and the method of the prior art (i.e., that the method of the prior art does not possess the same material method steps and parameters of the claimed method). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

#### ***Pertinent Prior Art***

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure (*Nanko et al*, WO 97/27889, published August 7, 1997).

#### **Status of Claims**

7. No claims are allowed.



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**Conclusion**

8. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (703) 308-4735. The examiner can normally be reached on Monday – Friday from 7:30 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.

  
Vanessa L. Ford  
Biotechnology Patent Examiner  
March 1, 2002

  
LYNETTE R. F. SMITH  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600